

REMARKS

Claims 1-13 and 15-18 were pending in the present application and were rejected on various grounds. Claims 1, 9 and 15 are amended, and claims 12 - 14 and 17 - 18 are cancelled without prejudice to more clearly claim the present invention and to expedite prosecution of the present application.

Claims 1, 3, 4, 5, 7, 9, 10, 12, 13, 15, 17 and 18 were rejected under 35 USC 102(b) as being anticipated by Tekulve ('953). The Examiner argues that Tekulve discloses a 'stent' comprising an expandable hoop support composed of material disposed to form a first coil and a second coil having memory properties and a rounded or ball end, and a second coil outer diameter configured to be larger than the target vessel size, and shows non-uniform spacing configured to allow blood flow therethrough, and further that Tekulve discloses a method of opening an artery by determining size and inserting the above device.

Applicant notes that Tekulve teaches an artificial *embolism* device to *occlude* the vessel and *inhibit* blood flow therethrough (Abstract, lines 1-2, 24-25, col. 2, lines 14, 27-28, etc.), that Tekulve discloses a monotonically increasing spacing between turns (col. 5, lines 46-55) apparently with the final turn (19) spacing being the largest. Moreover, Applicant is unable to locate a text or figure reference in support of her assertion that Tekulve teaches the step of determining size, especially in view of the disclosed helical spiral shape which tends to minimize the importance of determining artery size.

Applicant cancels claims 12 - 14 and 17, 18 without prejudice.

By contrast, the present invention according to claim 1, as amended, includes:

"a. a preformed hoop composed of material disposed to form a first coil which first coil is disposed to form a second coil having an outer diameter, having memory retaining properties, and having one of a rounded and a ball end, wherein said second coil further comprises
a beginning and an ending longitudinally disposed sections each having substantially uniformly spaced second coil loops, and
a middle section disposed between and contiguous with said beginning and end sections and comprising a loop having a loop spacing greater than said beginning and ending longitudinally disposed sections loop spacing, said middle section loop spacing being sufficient to provide non-occluding blood flow therethrough

not found in the cited art of record. Independent claim 9, as amended, provides similar patentably distinctive features. Tekulve teaches a conically helically shaped coil with increasing spacing (21) as the diameter increases, from which the claimed structure having a beginning and an ending longitudinally disposed section each having substantially uniformly spaced coil loops and a middle section disposed between the beginning and end sections and having a loop spacing greater than the beginning and ending loop spacing, is patentably distinguishable. Applicant therefore believes that independent claims 1 and 9 are patentably distinguished over the cited art of Tekulve, and that claims 3 and 4, dependent on claims 1 and claims 10 and 11, dependent on claim 9, include additional inventive features to further patentably distinguish the present invention over the cited art of record.

The invention according to claim 5, as previously amended, includes:

- a. determining an artery structure nominal opening size;
- b. providing a preformed hoop composed of a primary coil of material having one of a rounded and a ball end said primary coil being wound to encircle a second axis to form a secondary coil having an outer diameter matching said nominal opening size, and instilling memory retaining properties into said preformed hoop to urge said material into said double coil;
- c. providing a cylindrical delivery means for constraining said secondary coil into a linear configuration;
- d. inserting said hoop and said delivery means into an artery at said target site having an unsupported aperture size less than said nominal opening size; and
- e. removing said delivery means whereby said hoop remains in said artery to support said artery in an open position wherein said secondary coil outer diameter is larger than said target site unsupported aperture size and said secondary coil is configured to urge said target site aperture to said nominal opening size

not found in the cited art of Tekulve, which teaches reducing blood flow through the coil 15 (col. 2, line 12), occluding the vessel (col. 2, line 14) and embolization and providing an embolizing coil (col. 1, line 58), etc. from which the claimed procedure according to claim 5, including inserting a hoop which remains in the artery to support the artery in an open position, is patentably distinguishable. Moreover, the conical shape of Tekulve's coil 15 and teaching of vessel occlusion substantially obviates the need determine the artery structure nominal opening size as Tekulve (and apparently no such step is provided in Tekulve), and the invention of claim 5 includes determining the artery structure nominal opening size as well as inserting hoop which remains in the artery to support the artery in an open position. Applicant believes that

claim 5 is patentably distinguishable over the cited art of Tekulve, and claims 6 - 8 and 15 which depend on distinguished claim 5, provide further inventive features to further patentably distinguish the present invention over the cited art of record.

Claims 1-10, 12-13 and 15-18 were rejected under 35 USC 103(a) as being unpatentable over Brown et al ('199) in view of Jones ('560). The Examiner argues that Brown discloses a hoop support and procedure for opening an artery substantially as claimed, that Brown discloses a preformed hoop stent composed of a material formed into a first coil which is in turn formed into a second coil having a memory, and is adapted to hold open the vessel and thus inherently has a diameter larger than the vessel, has openings (e.g. 62, fig. 1) that allow some blood flow therethrough, and that the claimed rounded or ball ends are provided by Jones.

Applicant notes that Brown is directed to apparatus and methods for treating vessel aneurysms, wherein blood flow through the sided of the apparatus into the vessel aneurysm is undesirable and to be mitigated if not eliminated (col. 1, lines 1-19, col. 2, lines 47-64, etc.). The device 10 of Fig. 1A retains embolic masses to occlude the lumen (col. 4, lines 32-33). The modulator 80 (Fig. 6A) to divert blood flow away, apparently has loop spacing smaller than [beginning and ending] anchoring elements 30.

Applicant cancels claims 12 - 14 and 17, 18 without prejudice.

By contrast, the invention according to amended claim 1 includes a middle section disposed between and contiguous with said beginning and end sections and comprising a loop having a loop

spacing greater than said beginning and ending longitudinally disposed sections spacing, said middle section loop spacing being sufficient to provide non-occluding blood flow therethrough, and similarly for amended independent claim 9, patentably distinguishable from Brown or Jones, alone or in combination. The Examiner's conclusion that since Brown's device is anchored to the vessel that it "is adapted to hold open the vessel" is not supported by the teaching of Brown or Jones, as anchoring relates to restricting longitudinal movement in the vessel, and holding the vessel open is a result of radial forces perpendicular to the longitudinal dimension of the vessel. By contrast, in considering the prior art, it is expectable that a structure that is sufficient to anchor itself in a vessel (e.g. limit longitudinal motion) may be entirely insufficient to hold a vessel open, especially if it had been occluded. Moreover, there is no teaching that the spaces between the hoops 62 of Fig. 1 are larger than the spaces of the anchoring elements 30, and moreover are likely not to be larger especially in view of Brown's teaching to occlude the cavity (col. 4, lines 32, 33, col. 5, lines 1 - 10) and secure embolic masses (col. 4, lines 30 - 31) therein. Also note that when modifications or alternate embodiments of retainer 60 are discussed (col. 5, lines 10 - 35), many alternatives are mentioned, but none describe or suggest any differences between the spacing of the anchoring elements relative to the retainer 60, leaving the clear conclusion that Brown does not teach or suggest a wider spaced middle as claimed in claims 1 and 9. Applicant believes that independent

claims 1 and 9 are patentably distinguished over the cited art, and that claims 3 and 4, dependent on claims 1 and claims 10 and 11, dependent on claim 9, include additional inventive features to further patentably distinguish the present invention over the cited art of record.

Regarding the independent method claim 5, Brown's method and apparatus are entirely directed to occluding sidewall aneurysms, restricting blood flow and generating or retaining embolisms from which the claimed method, including inserting said hoop and said delivery means into an artery at said target site having an unsupported aperture size less than said nominal opening size, is patentably distinguishable. The Examiner's mere assertion that "Brown discloses the expandable hoop and method substantially as claimed..." provides an inadequate basis on which to base the rejection and an inadequate basis to enable Applicant to fully respond. Apparently in Brown, there are no apertures (e.g lesions, near-occlusions) of less than nominal vessel opening size. Applicant further argues that one skilled in the medical arts would treat the support of a dilated lesion entirely differently than Brown's inducing an embolic mass at an aneurysm, and that the Examiner's analogies are entirely without basis. Applicant believes that claim 5 is patentably distinguishable over the cited art of Brown, and claims 6 - 8 and 15 which depend on distinguished claim 5, provide further inventive features to further patentably distinguish the present invention over the cited art of record.

Applicant therefore believes that the rejection of claims 1, 3 - 5, 7 - 13, 15 and 17 -18 under 35 USC 103(a) as being anticipated by Brown ('199) in view of Jones is overcome.

Claims 1, 3 - 5, 7 - 15 and 17 - 18 were rejected under 35 USC 103(a) as being unpatentable over Farzia-Nia ('076) in view of Jones ('560), wherein the Examiner argues that Farzia-Nia discloses a expandable hoop support and procedure for opening an artery substantially as claimed. The Examiner states that Farzia-Nia discloses a preformed hoop stent (col 3, lines 47-50; col. 2, line 4) composed of a coil 10 of material comprising twisted multi-filar strands 12 forming strand 10 wound to form coil 14, and has memory, a cylindrical deliver means to constrain coil into a linear configuration, and wherein when delivery means is removed the coil reconfigures into an original preformed configuration, and is adapted to hold open the vessel (col 3, lines 47-50), an open or irregular spacing of the secondary coil (Fig. 3), such spacings adapted for placement near an opening in the vessel, and that Jones teaches a coil having rounded or ball ends.

Applicant cancels claims 12 - 14 and 17, 18 without prejudice.

Applicant notes that stents may be used for purposes other than holding open a dilated vessel, e.g. for support during an anastomosis, and that the term 'stent' is not limited to a single defined structure or function. Indeed, Farzia-Nia refers to a stent only as a form of a coil spring (col 2, lines 2-7).

Applicant further notes that Farzia-Nia only suggests that the disclosed stranded wire could be used in a stent of undisclosed

structure or method. Moreover, Applicant is unable to discern any openings or irregular spacing in the secondary coil 14, which even where joined at 22 appear to be uniformly spaced and abutting.

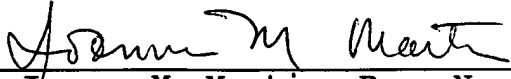
Regarding amended independent claim 1 which includes a middle section disposed between and contiguous with said beginning and end sections and comprising a loop having a loop spacing greater than said beginning and ending longitudinally disposed sections spacing, said middle section loop spacing being sufficient to provide non-occluding blood flow therethrough, and similarly for amended independent claim 9, Farzia-Nia is completely silent, teaching instead uniformly spaced, abutting loops. The sole disclosed complete structure of Fig. 3 relates to orthodontic brackets and is entirely unrelated to the claimed structure, nor can it be modified to provide the claimed structure except by undue experimentation. Applicant believes that independent claims 1 and 9 are patentably distinguished over the cited art, and that claims 3 and 4, dependent on claims 1 and claims 10 and 11, dependent on claim 9, include additional inventive features to further patentably distinguish the present invention over the cited art of record.

Regarding independent method claim 5, Farzia-Nia's sole disclosed step is inserting stranded wires into the body through a tube, (col. 3, lines 23-25) as used for guide wires, from which the present claimed invention which includes the steps of determining an artery structure nominal opening size and inserting said hoop and said delivery means into an artery at said target site having an unsupported aperture size less than said nominal opening size,

is patentably distinguishable. If the Examiner is inferring such claimed steps from Farzia-Nia's reference to a stent, Applicant respectfully requests that the Examiner state so (or otherwise indicate the origin of such steps in Farzia-Nia) and provide supporting references so that Applicant can fully respond. Claims 6 - 8 and 15 which depend on distinguished claim 5, provide additional inventive features to further patentably distinguish the present invention over the cited art of record. Applicant therefore believes that the rejection of claims 1, 3 - 5, 7 - 13, 15 and 17 -18 under 35 USC 103(a) as being anticipated by Farzin-Nia ('076) in view of Jones is overcome.

Applicant, having amended the Claims, and having distinguished the present invention over the cited art of record, believes that the present application is in condition for allowance. Applicant respectfully requests reconsideration and allowance of the present application. The Examiner is invited to call the Applicant's undersigned attorney should she feel that such a call would further the prosecution of the present application.

Respectfully submitted,
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